



Docket No. 212/291

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:

Mollenauer, et al.

Serial No.: 09/724,325

Filed: November 28, 2000

For: Resuscitation Device

Art Unit: 3734

Examiner: DeMille, D.

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REPLY TO EXAMINER'S ANSWER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is responsive to the Examiner's Answer dated April 6, 2004.

Summary

The grounds for rejection stated in the Examiner's Answer fail to establish that Lach et al., Resuscitation Method and

Certificate of Mailing (37 CFR 1.10)

I hereby certify that this response (along with any paper referred to as being attached or enclosed) is being deposited in Express Mail using Express Mail Post Office to Addressee with the United States Postal Service on the date shown below in an envelop addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Express Mail No. EL 965834895 US

Date: June 7, 2004

Theodore D. Fay III

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Apparatus, United States Patent 4,770,164 (Sep. 13, 1988) discloses or inherently contains the claimed limitation of a friction liner adapted to extend substantially completely around the chest of a human. The Examiner's Answer asserts that the shirt in Lach would function as a friction liner as claimed to at least a certain extent. As discussed below, this assertion is erroneous. Moreover, because Lach does not mention the shirt in his description, the statement is unsupported speculation that cannot sustain an anticipation rejection. In addition, the Examiner's Answer asserts that the PTFE liner disclosed in Lach could, under certain circumstances, extend "substantially completely around" the chest of a patient as claimed. As discussed below, this assertion is also erroneous. Moreover, because the assertion is based on the Examiner's speculation and not on Lach's disclosure, the assertions are insufficient to establish that Lach expressly or inherently shows the limitations at issue. Thus, Lach does not anticipate the claims.

The reasoning supporting the rejections is insufficient to sustain anticipation rejections of the claims. The Examiner's Answer fails to point to any text in Lach that explicitly discloses the limitations at issue. The text and figure cited in the Examiner's Answer are merely a starting point for the Examiner's unsupported speculations regarding how the shirt functions and how Lach would operate with differently sized patients. Anyone reading Lach will find that Lach does not discuss the shirt; thus, the Examiner must speculate as to how one of ordinary skill in the art of CPR devices would think the shirt would function. Anyone reading Lach will find that Lach does not disclose the Examiner's scenario regarding large and small patients. Thus, although the Examiner's Answer couches its statements in terms of what Lach discloses, in actuality the Examiner's Answer implicitly admits that Lach does not explicitly disclose the limitations at issue. Thus, the grounds for rejection must rely on what is inherently present in Lach. For

the claimed limitations to be inherently present in Lach, the missing descriptive material must be necessarily present in Lach, not merely probably or possibly present in Lach. Rosco Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002). As shown below, the limitation at issue is not necessarily present in Lach and, in fact, cannot be present in Lach. Therefore, Lach does not inherently show the limitation at issue. Therefore, in the light that Lach does not explicitly show the limitation at issue, Lach does not anticipate the claims.

Declarations Submitted to Counter New Factual Assertions in the
Examiner's Answer

In a section directed to a new argument that, when used on a child, Lach would include the claimed friction liner, the examiner makes numerous factual assertions and speculations that are completely wrong. Because the Examiner is asserting speculative new facts, Applicant is entitled to present evidence, including declarations, to rebut the Examiner's erroneous statements. The declarations of David R. Kalman, K. David Crockett and Theodore D. Fay III are attached to this appeal brief. Applicants request that the board consider the declarations for purposes of negating the new factual assertions made by the Examiner.

The Examiner's Factual Assertions Regarding Child Use of the
Device Are Plainly Incorrect

First, the examiner states that Lach teaches that it may be necessary to use a PTFE sheet near his base. This is incorrect. Lach explicitly teaches that it is unnecessary:

Friction against the rear portion 32 of the thorax can be further reduced by placing a thin sheet of polytetrafluoroethylene resin plastic between the patient and

the base 34 and the contoured portions 20 and 22, *but this is at present believed to be unnecessary.*

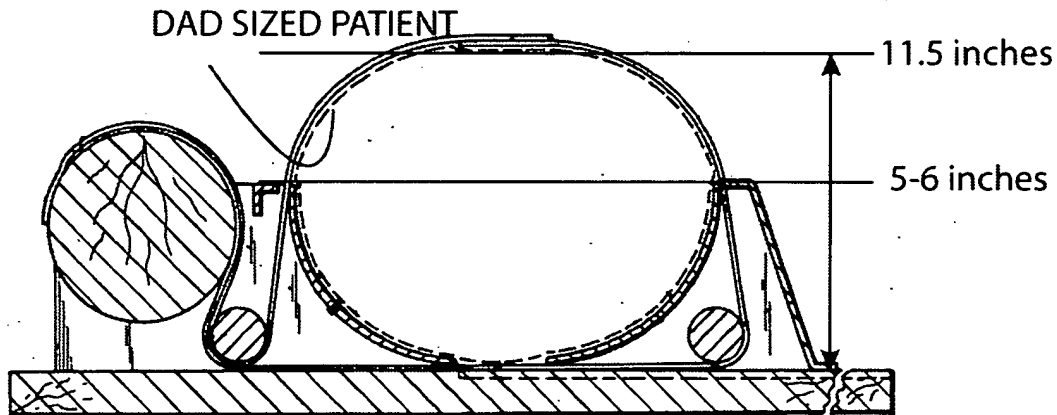
Lach, column 6, lines 57 through 61 (emphasis added.)

Next, the examiner states that to accommodate really large patients, the right chock 22 would be slid to the top of the track 48. This is incorrect. This is the condition of the device in typical use, as shown in Figure 3, which is presumably not depicting an aberrant case. In typical use, the chock 22 is slid to the outer extent of the device, as shown in Lach's illustrations.

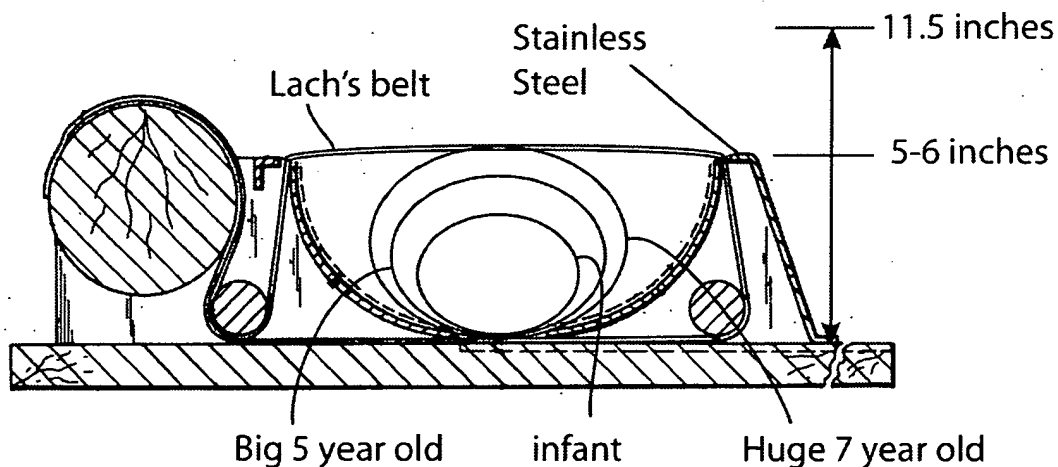
Next, the examiner states that sliding the chock would produce a "very" large gap between the two chocks, and so the sheet would have to be large enough to cover the gap, and that this same sheet would be used for all sized people because EMTs will not have a ready supply of differently sized sheets for differently sized people. This speculation is totally unfounded and demonstrably incorrect. Even while responding to a cardiac arrest, EMTs routinely carry and apply differently sized devices for differently sized patients. Intubation tubes, face masks, needles, laryngoscopes and laryngoscope blades, and defibrillation pads and paddles of different sizes are carried by EMTs and applied as the patient's size dictates. This is particularly true of child cardiac arrest victims, for which juvenile and infant devices must be used. See Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care pp. I-132, I-300, I-308 (American Heart Association, 2000) and Kalman dec. ¶¶ 5 and 6. There is no reason that a new tool such as the Lach device would not be provided in sizes, or that EMTs could not provide differently sized components for the device. Thus, the Examiner's unfounded assertion is clearly wrong and there is no basis to assume that an EMT will not select an appropriately sized PTFE sheet when using Lach's device during emergency CPR, even if a sheet is used. Thus, there is no basis to assume that the claimed

limitations regarding a friction liner adapted to be disposed substantially completely around the patient's chest are necessarily present in Lach. Accordingly, Lach does not anticipate the claims.

Next, the Examiner states that when the Lach device is used for very small children, the same liner would completely surround the child's chest. The statement is baseless and wrong. Unless the chocks are provided in different sizes, the device will provide utterly no compression to a very small child, or a small child, or even a large child. The chocks are made of stainless steel, according to Lach. The chocks extend about half the height of the prone thoracic thickness show in Lach's figure 3. If the person shown in Figure 3 is the Examiner's very large human (for which chock 22 would be shifted to the farthest extent, as hypothesized by the Examiner), he might have a thoracic circumference of 46 inches and a thickness of 11.5 inches (we measured the biggest guy we could find). Fay dec. ¶ 3. The chocks would then be about 6 inches high. A huge seven year old whom we measured had a thoracic circumference of 25 inches and a thickness of 6 inches. Crockett dec. ¶ 2. A big five year old had a thoracic circumference of 23 inches and a thickness of 5 inches. Crockett dec. ¶ 2. A big 7 month old infant had a thoracic circumference of 21 inches and a thickness of 4 inches. Fay dec. ¶ 2. Obviously, the device would not compress any of these children because the belt would be suspended above them by the stainless steel chocks. This is show in the following illustrations:



In this first illustration, the patient is a big Dad-sized human (not necessarily the very large person the Examiner envisions), which may be contemplated by Lach. The dimensions are for a typical man with a thoracic circumference of 46 inches and a thoracic thickness of 11.5 inches. The chocks as shown in Lach appear to be over half the height of the patient.



In this second illustration, the same size device used for the Dad-sized patient is shown with a few child-sized patients in the device. The 7 year old child is 54 inches tall, with a thoracic circumference of 25 inches and a thoracic thickness of 6 inches. Clearly, the belt would barely impinge on the child's chest, and would provide no compression. The 5 year old child is 44 inches tall, with a thoracic circumference of 23 inches and a thoracic

thickness of 5 inches. The infant is 28 inches long, with a thoracic circumference of 21 inches and a thoracic thickness of 4 inches. Clearly, the belt cannot compress these children, and the device cannot, as suggested by the Examiner, be used on any child, much less a very small child.

Obviously, Lach's entire device would have to be downsized for pediatric use, and there is no indication that the downsizing would be accomplished selectively. But the necessary downsizing proves that the Examiner's assertion that EMTs can't be bothered with selecting components of appropriate size for cardiac arrest victims is incorrect. It also proves that the Examiner's speculative modification is inoperable and therefore not inherently present in Lach. Accordingly, Lach does not anticipate the claims.

Lach Does Not Disclose a Shirt that Functions as a Friction Liner

The examiner states that Lach's shirt could function as a friction liner, but this is not supported by Lach. As Lach explicitly states, friction is not a problem in his device. (Lach, column 6, line 61.) Thus, there is no reason to assume that Lach inherently provides for a friction liner in the form of the shirt shown in figure 1 of Lach. However, Lach's statement gives one of ordinary skill a good reason to assume that the shirt is not a friction liner. Because Lach's shirt is not necessarily a friction liner, the shirt shown in Figure 1 of Lach is not inherently a friction liner. Accordingly, Lach does not anticipate the claims.

In addition, the Examiner's Answer speculates that the shirt shown in Lach is a friction liner because it might operate as a friction liner under some conditions. The Examiner's assertion that there will be some slippage between the shirt and the belt is contrary to Applicants' real-world experience and is erroneous.

In Applicant's experience, as presented in arguments in the prior office action responses in this case, the belt will catch on the shirt and rub the shirt across the patient's chest. Friction arises between the shirt and the patient's skin, between the patient's connective tissues, between the belt and shirt and between the belt and the skin while a belt-driven device is in operation. Kalman dec. ¶ 4. In practice, Applicants have seen that in belt-driven resuscitation devices the shirt will exacerbate the frictional drag on the system and the frictional effects on the belt on the patient, leading to reduced battery life and lacerations or bruising on the patient. Kalman dec. ¶ 4. Because the shirt is actually a source of friction, Lach does not necessarily show that the shirt is a friction liner and, in fact, cannot show it at all. Accordingly, Lach cannot anticipate the claims.

Moreover, the Examiner's Answer contends that if the shirt were made of a low-friction material or if some slippage occurs between the belt and the shirt, then Lach does "comprehend" a friction liner. However, the Examiner's assertions cannot replace the lack of disclosure in Lach and there is no basis to assume that the shirt in figure 1 is necessarily made of a low-friction material or that slippage will necessarily occur between a belt and the shirt. Thus, the shirt of figure 1 is not inherently a friction liner. Accordingly, Lach does not anticipate the claims.

The PTFE Sheet Shown in Lach Does Not Inherently Wrap
Substantially Around the Chest of the Patient

The Examiner's Answer contends that if the shirt shown in figure 1 of Lach is not a friction liner, then Lach discloses the use of a polytetrafluoroethylene (PTFE) sheet that could wrap around the chest of a patient; thereby anticipating the claims. The Examiner's Answer also contends that the term "chest" includes

the entire trunk of a human. Accordingly, the Examiner's Answer contends that because Lach shows the PTFE sheet disposed between the patient's back and the belt, that Lach shows a friction liner wrapped around the chest.

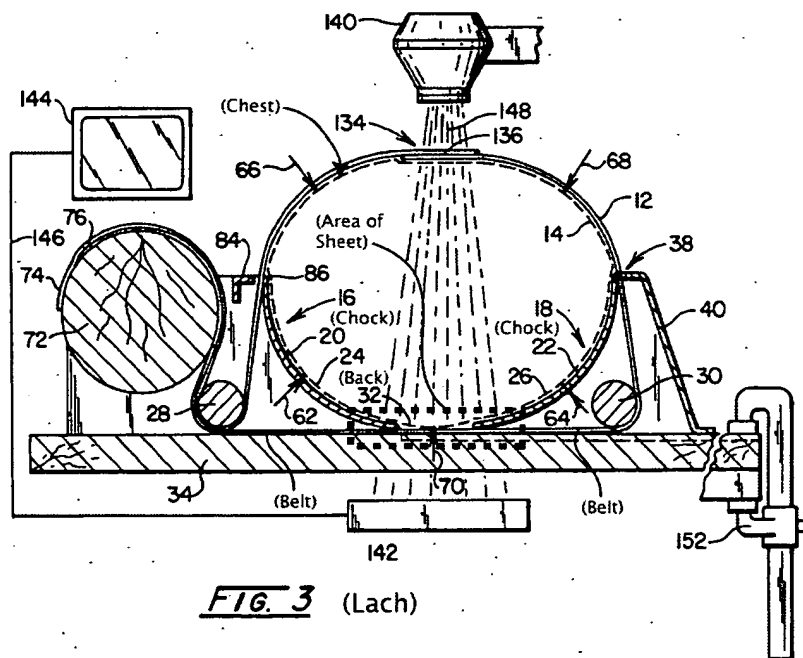
The Examiner's assertions are not shown in Lach and therefore Lach does not explicitly show the claimed limitations. Furthermore, the Examiner's assertions incorrect and Lach does not inherently show the claimed limitations.

Regarding the definition of the word "chest," anyone of ordinary skill in the art of CPR devices knows that the chest is the anterior aspect of the thorax. (Steadman's Medical Dictionary 331, 27 ed. 2000). (The Examiner's Answer refers to a dictionary to support its definition of "chest," but provides no citation for Applicant or the Board to review. Since the relevant art is CPR devices, the Board should rely on an internationally recognized medical dictionary and not on an unsupported citation to determine the meaning of the word "chest.") To those of skill in the art of CPR devices and to anyone of skill in the medical arts, the area that the Examiner contends is the chest is actually the thorax. Id. at 1829. Anyone of ordinary skill in the art knows the difference between the thorax and the chest. Lach's PTFE sheet is disposed between the back and the belt, not between the chest and the belt. Thus, anyone of ordinary skill reading Lach will immediately understand that Lach does not show a friction liner adapted to extend substantially completely around the chest of the patient. Furthermore, in view of Lach's complete lack of disclosure on the subject, no basis exists to assert that the claimed limitation is inherently present in Lach. Thus, Lach does not anticipate the claims.

The Examiner's Answer contends that Applicant's drawing shows a narrow interpretation of Lach's disclosures and that Applicant "has failed to take into consideration that the sheet would have to comprehend patients of different sizes." Applicant's modified

drawing of Lach's figure 3 reflects Lach's explicit disclosures. The modified version of figure 3, as reproduced below, shows that Lach does not explicitly disclose the claimed limitations.

However, the interpretation of Lach's disclosures is not at issue, except to the extent that the interpretation is relevant to the determination of whether the claimed limitations are inherently present in Lach. Even if Lach were resized for differently sized patients, the PTFE sheet would remain (absent unsuggested selective downsizing of components) under the patient's back. Therefore, Lach does not in any sense show the limitation of a friction liner wrapped substantially completely around the chest of the patient. Accordingly, Lach does not anticipate the claims.

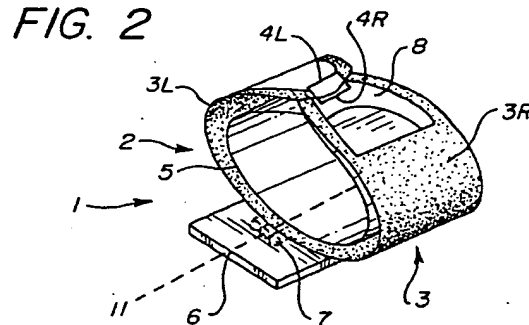


The Examiner's interpretation of the size of Lach's PTFE sheet is insufficient to establish that the PTFE sheet is necessarily adapted to extend substantially completely around the chest of a human as claimed. Even if the Examiner's speculation regarding patient sizes seems plausible (which it does not), the

size and use of the Lach PTFE sheet must *necessarily* show the limitation of a friction liner adapted to extend substantially completely around the chest of the patient to anticipate the claimed limitation. However, Lach states that the sheet is *unnecessary*. Lach, column 6, line 62. Thus, there is no reason to believe that a PTFE sheet large enough to encompass the claimed limitations is *necessarily* present in Lach. Accordingly, Lach does not anticipate the claims.

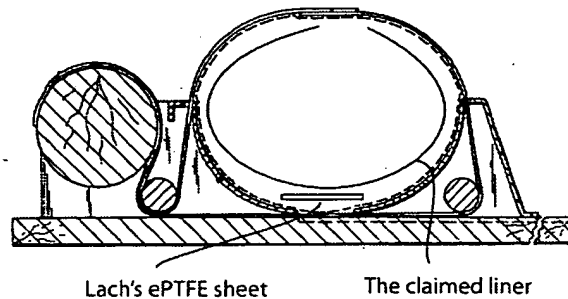
Applicants Language Is Sufficiently Distinct from Lach's Structure
To Avoid the Confusion Expressed by the Examiner

The claim language describes Applicant's device as accurately as the English language allows. The claimed device is shown in Applicant's Figure 2, reproduced below:



Clearly, the claimed friction liner (item 5) wraps around the patient's back and sides and completely around the chest. To protect against an insignificant variation (for example, leaving the sternal depression unprotected) Applicants have chosen to claim that the friction liner extends substantially completely around the patient's chest.

Lach's PTFE sheet is clearly distinct in structure, as shown the by the drawing on the following page:



Again, the claimed friction liner wraps around the patient's back and sides and substantially completely around the chest. Lach's PTFE sheet, as described by Lach, at most occupies a small space next to the patient's back. The Examiner's assertions otherwise are unsupportable speculation that cannot sustain an anticipation rejection.

There can be no confusion between the small PTFE sheet near the back shown by Lach and the large friction liner ("substantially completely around the chest") claimed by Applicant. Thus, Lach does not inherently show the claimed limitations. Accordingly, Lach does not anticipate the claims.

The Examiner's Answer asks, "At what point less than completely around the chest would be comprehended by the claims?" The answer to the Examiner's question is ascertainable under current legal standards. Expressions such as "substantially" are used in patents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention. Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120 (Fed. Cir. 2002). (The term "substantially" has been used in the claims of 771,870 patents as of June 1, 2004, thereby indicating that the term complies with United States patent law.) However, Lach discloses nothing that would require only a "minor variation" to achieve the claimed limitations. Instead, the Examiner's proposal requires a significant departure from the disclosures in Lach - a departure that Lach does not suggest and that Lach strongly implies is unnecessary. Thus, it remains true

that the claimed limitation is not expressly or inherently present in Lach. Accordingly, Lach does not anticipate the claims.

The Examiner's Answer also asserts that Applicant asserts that in one instance Lach's sheet may not extend substantially around the chest of the patient and therefore "doesn't comprehend the claims." (The Examiner's Answer then repeats the speculative assertion regarding a large sheet used on a small patient.) The Examiner's Answer misunderstands Applicants' argument and the law regarding inherent anticipation. By providing at least one counter-example, Applicant has shown that the claimed limitation is not inherently present in Lach. Thus, Lach cannot anticipate the claims regardless of any speculative use of Lach's device.

The Examiner's Answer also asserts that the limitation that the friction liner is adapted to extend substantially completely around the chest of a human is different from Lach only as a matter of degree. This assertion is incorrect. The behavior of a CPR device and its hemodynamic effect on a patient differs with even small changes to the device. Thus, modifying Lach's PTFE to meet the claimed limitations results in a qualitatively new CPR device. Given that the modification is unsuggested, that the modification would likely change the hemodynamic effect Lach's device produces, and that a person's life will be at stake, there is no basis to assert that the Lach's sheet and Applicant's claimed inventions are different only to a matter of degree. In addition, the issue is whether Lach explicitly or inherently shows the claimed limitation, not whether a difference is a "matter of degree." By stating that the difference is only "a matter of degree," the Examiner has already admitted that Lach would have to be modified to result in the claimed inventions. Thus, again, the claimed limitation is not inherently present in Lach. Accordingly, Lach does not anticipate the claims.

Lach does not explicitly or inherently disclose the claimed limitation of a friction liner adapted to extend substantially

completely around the chest of a human. Thus, Lach cannot anticipate any of the claims, notwithstanding any speculative assertions made by the Examiner.

Conclusion

The Examiner's Answer does not overcome the fundamental flaws with the rejection: That the limitations at issue are not explicitly disclosed by Lach and are not necessarily present in Lach. Because Lach does not expressly or inherently disclose a friction liner adapted to extend substantially completely around the chest of a patient, Lach does not anticipate the claimed inventions. Accordingly, the rejections should be reversed and the claims allowed.

This reply brief has addressed the Examiner's Answer. Applicants request that the rejection of the claims be reversed and that the claims be allowed.

Date: June 7, 2004

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